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| SERIAL NUMBER | FILING DATE | FIRST NAMED APPLICANT | ATTORNEY DOCKET NO. |
|---------------|-------------|-----------------------|---------------------|
| 06/854,739    | 04/21/86    | BRANDSTROM            | A 25995A-FWC-A      |

BRUMBAUGH, GRAVES, DONOHUE & RAYMOND  
30 ROCKEFELLER PLAZA  
NEW YORK, NY 10112

| EXAMINER |              |
|----------|--------------|
| FAN, J   |              |
| ART UNIT | PAPER NUMBER |
| 121      | 22           |

DATE MAILED: 10/24/86

This is a communication from the examiner in charge of your application.  
COMMISSIONER OF PATENTS AND TRADEMARKS

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☒ This application has been examined ☐ Responsive to communication filed on \_\_\_\_\_ ☐ This action is made final.

A shortened statutory period for response to this action is set to expire 3 month(s), \_\_\_\_\_ days from the date of this letter.  
Failure to respond within the period for response will cause the application to become abandoned. 35 U.S.C. 133

Part I THE FOLLOWING ATTACHMENT(S) ARE PART OF THIS ACTION:

- |   |   |
|---|---|
| 1. <input checked="" type="checkbox"/> Notice of References Cited by Examiner, PTO-892. | 2. <input type="checkbox"/> Notice re Patent Drawing, PTO-948.                  |
| 3. <input type="checkbox"/> Notice of Art Cited by Applicant, PTO-1449                  | 4. <input type="checkbox"/> Notice of informal Patent Application, Form PTO-152 |
| 5. <input type="checkbox"/> Information on How to Effect Drawing Changes, PTO-1474      | 6. <input type="checkbox"/> _____   |

Part II SUMMARY OF ACTION

1. ☒ Claims 1-7, 16-31 are pending in the application.  
Of the above, claims 5-7 are withdrawn from consideration.
2. ☐ Claims \_\_\_\_\_ have been cancelled.
3. ☐ Claims \_\_\_\_\_ are allowed.
4. ☒ Claims 1-4, 16-31 are rejected.
5. ☐ Claims \_\_\_\_\_ are objected to.
6. ☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.
7. ☐ This application has been filed with informal drawings which are acceptable for examination purposes until such time as allowable subject matter is indicated.
8. ☐ Allowable subject matter having been indicated, formal drawings are required in response to this Office action.
9. ☐ The corrected or substitute drawings have been received on \_\_\_\_\_. These drawings are ☐ acceptable; ☐ not acceptable (see explanation).
10. ☐ The ☐ proposed drawing correction and/or the ☐ proposed additional or substitute sheet(s) of drawings, filed on \_\_\_\_\_, has (have) been ☐ approved by the examiner. ☐ disapproved by the examiner (see explanation).
11. ☐ The proposed drawing correction, filed \_\_\_\_\_, has been ☐ approved. ☐ disapproved (see explanation). However, the Patent and Trademark Office no longer makes drawing changes. It is now applicant's responsibility to ensure that the drawings are corrected. Corrections MUST be effected in accordance with the instructions set forth on the attached letter "INFORMATION ON HOW TO EFFECT DRAWING CHANGES", PTO-1474.
12. ☒ Acknowledgment is made of the claim for priority under 35 U.S.C. 119. The certified copy has ☒ been received ☐ not been received  
☐ been filed in parent application, serial no. \_\_\_\_\_; filed on \_\_\_\_\_.
13. ☐ Since this application appears to be in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11; 453 O.G. 213.
14. ☐ Other

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Claims 1-4, 16-30 are rejected under 35 USC 103 as being unpatentable over Senn-bilfinger, EP 5129, EP45200, Narisada et al (newly cited) all considered together. Applicant's declaration together with his arguments has been carefully considered, but is deemed unpersuasive for the following reasons:

1. It is not clear whether the choice of applicant's testing condition as 50°C sealed and 37°C at relative humidity is arbitrary or by art-recognized procedure. If it is by art-recognized procedure, applicant is requested to submit such references with pertinent part underlined for examiner's consideration.

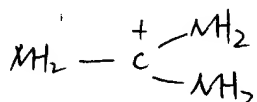
2. It appears that chemical decomposition by heat (50°C) is different from air decomposition, some chemicals may be very stable in air yet they are unstable in heat. There is no general rule to correlate the air decomposition (usually the chemical is covered tightly) of a chemical with heat decomposition.

3. The difference of the test data showing 94-96% stability of the pure ~~at~~ compound<sup>0</sup> versus 98-99% stability of the claimed compound is of degree only, not of kind.

4. The evidence presented is not commensurate with the scope of the generic claim. A person skill in the art would expect that Li salt, Na salt, K salt,

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all mono-valent would behave in similar manner.  
 The same rationale would apply to Mg and Ca salts.  
 However, Ti salt,  $N+(R')_4$  salt and



salt are very different. The result of the latter three salts could not be extrapolated from the result of monovalent or divalent salt.

5. ~~Assuming~~ <sup>Even if</sup> applicant's declaration and arguments are convincing, it appears that the reported results in stability are expected since pharmaceutically base addition salts are known to be more soluble or more stable (pat. 4323567, col. 3, lines 43-48). It is only when the greater stability would not have been expected <sup>then</sup> ~~that~~ it may constitute a basis for patentability. If the beneficial results shown for a compound would have been expected, said results are evidence of obviousness, rather than unobviousness. In re Gershon, 54 CCPA 1066, 372 F.2d 535, 152 USPQ 602 (1967); In re Skoll, 523 f.2d 1392, 187 USPQ 481 (CCPA 1975); In re Hoffman, 556 F.2d 539, 194 USPQ 126 (CCPA 1977).

A title more descriptive of the claimed invention should be used.

JTFan:ce  
 A/C 703-557-1456  
 10-23-86

*Jane T. Fan*  
 JANE T. FAN  
 PRIMARY EXAMINER  
 ART UNIT 121

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